

Rejection under the judicially-created doctrine of double-patenting

Claims 16 and 29-34 are rejected under the judicially created doctrine of double patenting over claim 5 of U.S. Patent No. 6,649,647, Hayes et al. since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: In the instant claims, in formula (1), Y is defined to be –NR1R2 where R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted nonaromatic heterocyclic group. Claim 5 of the '647 patent teaches variable "A" which corresponds to variable "Y" of the instant claims. In the '647 patent, A is defined to be –NR3R4 wherein R3 and R4 together with the interjacent nitrogen atom represent an optionally substituted heterocyclic group. Therefore, the subject matter of instant claims 16, and 29-34 is encompassed in claim 5 of the '647 patent. The '647 patent provides motivation to prepare the compounds in claims 16 and 29-34 through the species Examples in column 35, lines 33-38. Further motivation is provided in the '647 patent in column 10, lines 50-55, which states that "In a further preferred aspect, Y may represent a group –NR3R4 where . . . R3 and R4 together with the interjacent nitrogen atom represent a 5 to 10- membered heterocyclic group."

The present application and USP 6,649,647 were under a common obligation of assignment to The Hong Kong University of Science & Technology at the time both inventions were made. Subsequently The Hong Kong University of Science and Technology transferred title to Bayer AG, which has by contract transferred its rights to Bayer Business Services GmbH, which has in turn transferred its rights by contract to Bayer HealthCare AG. Assignment of title in the U.S. has not yet taken place between Bayer AG and Bayer HealthCare AG.

Enclosed is a terminal disclaimer of the present application over USP 6,649,647 by Bayer AG, the current owner of this application. Bayer Business Services GmbH and Bayer HealthCare AG are in accord with this terminal disclaimer.

Rejection under 35 USC 102(b):

Claims 16 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1122806, Li et al. (STN International 1999:234337; RN 221890-88-6 and RN 221890-90-0, Abstract).

RN 221890-88-6 anticipates the instant compound when in the instant compounds, Y is $-NR_1R_2$ wherein R1 and R2 together with the interjacent nitrogen atom represent 9H-purin-6-amine.

RN 221890-90-0 anticipated the instant compound when, in the instant compounds, Y is $-NR_1R_2$ wherein R1 and R2 together with the interjacent nitrogen atom represent 1H-1,2,4-triazole-3-carboxamide.

The abstract in STN International discloses that the compound of Li et al. is useful in antitumor agents.

Claim 16 is directed to compounds of formula 1 in which Y is $-NR_1R_2$ where R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted nonaromatic heterocyclic group.

Claim 23 is directed to a pharmaceutical composition comprising a carrier and, as an active ingredient, a compound of the general formula 1 according to Claim 16.

9H-purin-6-amine and 1H-1,2,4-triazole-3-carboxamide represent aromatic heterocycles and accordingly do not anticipate the present claims.

Rejection under 35 USC 112, second paragraph:

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, R1 and R2 together with the interjacent nitrogen atom represent an optionally substituted non-aromatic heterocyclic group. However, it is unclear what substituents may appear on the heterocyclic group. For example, the elected species, Example 7, contains two oxo groups on the sulfur in the thiomorpholine ring. However, the term "oxo" does not appear in the list of substituents on page 11, lines 17-23. Clarification is requested regarding whether dioxothiomorpholine is the only compound intended to have oxo groups as substituents on the heterocyclic group.

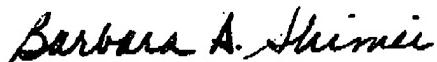
Claim 28 is rejected for being dependent on claim 16.

The term "dioxothiomorpholino" is a synonym for "morpholinosulfonyl" but the compound of Example 7 is not considered a substituted thiomorpholino. Oxidized sulfur is in general not considered a "substituted" sulfur, but a separate chemical entity, e.g. a sulfoxide, sulfur dioxide, sulfonyl, sulfonic acid, etc. The nomenclature allows organic compounds containing sulfur to be referred to as "oxo-thio" and the like but this does not imply a "substituted" sulfur. The synonym "morpholinosulphonyl" shows this clearly. See also p. 10 lines 26-27 where morpholinosulphonyl as well as thiomorpholinyl are listed as different heterocycll species suitable for use in the present invention. As the dioxothiosulphonyl/morpholinosulphonyl is not considered substituted, "oxo" is not listed as a substituent on page 11, lines 17-23. Therefore it is clear to a person skilled in the art that the oxo moiety is an integral part of the dioxothiosulphonyl/morpholinosulfonyl heterocycle and is not intended as a substituent on other heterocycles.

The Commissioner is hereby authorized to charge any fees required as a result of this Amendment to Deposit Account 13-3372. A duplicate of this sheet is enclosed.

For the foregoing reasons it is believed this application is now in condition for allowance and such action is earnestly solicited.

Respectfully submitted,



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